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Vivex Biomedical Inc.
David L. King
5131 NE County Road 340
High Spring, FL 32643

EXAMINER

IWAMAYE, ANDREW MICHAEL

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THEODORE MALININ and TEMPLE H. THOMAS

Appeal 2015-003009
Application 13/057,918¹
Technology Center 3700

Before MICHAEL C. ASTORINO, JAMES A. WORTH, and
KENNETH G. SCHOPFER, *Administrative Patent Judges*.

SCHOPFER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the rejection of claims 1–17 and 34–38. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

BACKGROUND

According to Appellants, “[t]he present invention is generally directed toward composite bone grafts, surgical implant assemblies comprising the composite bone grafts, and methods of using the same.” Spec. ¶ 1.

¹ According to Appellants, the real party in interest is the University of Miami. Appeal Br. 3.

CLAIMS

Claims 1–17 and 34–38² are on appeal. Claim 1 is the only independent claim on appeal and recites:

1. A composite graft comprising:

a first bone dowel having the shape of a frustum, said first bone dowel having a first proximal end and a first distal end and a first axial bore extending from the first proximal end to the first distal end, wherein said first distal end has an area greater than an area of said first proximal end; and

a ligament replacement graft with a first end and a second end, wherein said first end is attached to said first bone dowel within said first axial bore such that the first proximal end of said first bone dowel is closer to the second end of said ligament than the first distal end,

wherein said first bone dowel comprises:

(a) a bone component comprising particulate bone of between 75 and 600 microns, powdered bone of 75 microns or smaller in size, or both, and

(b) biocompatible solid comprising a calcium sulfate hemihydrates, a calcium phosphate product, or both; and wherein said ligament replacement graft is structured and configured to produce a constant tension to retain said first bone dowel at a first site of surgical installation.

Br. 17.

² Claims 18–33 are withdrawn. *See* Br. 21–25.

REJECTIONS

1. The Examiner rejects claims 1, 3–5, 10, 11, 15–17, and 35–38 under 35 U.S.C. § 103(a) as unpatentable over Lambert³ in view of Boyce.⁴
2. The Examiner rejects claims 1 and 2 under 35 U.S.C. § 103(a) as unpatentable over Lambert in view of Meredith.⁵
3. The Examiner rejects claims 6, 7, and 34 under 35 U.S.C. § 103(a) as unpatentable over Lambert in view of Boyce and Semple.⁶
4. The Examiner rejects claims 6, 7, and 34 under 35 U.S.C. § 103(a) as unpatentable over Lambert in view of Boyce and Mansat.⁷
5. The Examiner rejects claims 8, 9, 12, and 13 under 35 U.S.C. § 103(a) as unpatentable over Lambert in view of Boyce and Enzerink.⁸
6. The Examiner rejects claims 12–14 under 35 U.S.C. § 103(a) as unpatentable over Lambert in view of Boyce and Bianchi.⁹

DISCUSSION

With respect to claim 1, the Examiner finds that Lambert teaches a composite graft including a first bone dowel and a ligament replacement graft as claimed except that Lambert does not teach a bone dowel “made from the claimed composition.” Final Act. 4–5 (citing Lambert Fig. 24).

³ Lambert, M.D., US 2008/0027443 A1, pub. Jan. 31, 2008.

⁴ Boyce et al., US 2003/0039676 A1, pub. Feb. 27, 2003.

⁵ Meredith, US 2003/0036800 A1, pub. Feb. 20, 2003.

⁶ Semple et al., US 3,973,277, iss. Aug. 10, 1976.

⁷ Mansat et al., US 5,108,431, iss. Apr. 28, 1992.

⁸ Enzerink et al., US 2002/0165611 A1, pub. Nov. 7, 2002.

⁹ Bianchi et al., US 2006/0212036 A1, pub. Sept. 21, 2006.

The Examiner finds that both Boyce and Meredith disclose bone graft material as claimed. *Id.* at 5 (citing Boyce ¶¶ 71, 84, 87), 8 (citing Meredith ¶¶ 59, 71, 72, 79; claim 48). The Examiner concludes that it would have been obvious to modify Lambert’s bone dowel to include the claimed composition, as taught by Boyce or Meredith, “in order to employ an alternative bone composition that promotes bone tissue formation.” *Id.* (citing Boyce ¶¶ 8–10; Meredith ¶ 42). The Examiner also finds that Lambert modified with either Boyce or Meredith would be structurally identical to the claimed device and would be inherently capable of producing a constant tension to retain the first bone dowel at the site of surgical installation, as claimed. *Id.* at 6, 8. Finally, the Examiner also finds that “the claims do not preclude the use of cements or glues as taught in Lambert to help retain the dowel in place. In [either proposed] combination, a mixture of cement/glue and tensile forces naturally assist in retaining the bone dowel within the bone.” *Id.* at 6, 9.

Appellants address both rejections of claim 1 together and raise several arguments: 1) the Examiner conclusion that the combination is inherently structured to produce constant tension to hold the bone dowel in place is conclusory and incorrect because Lambert teaches using bone cement for anchoring to the bone; 2) the invention is not a predictable result from the proposed combination; 3) the examples in the Specification show the invention overcomes a long-felt but unsolved need; and 4) that the prior art teaches away from the claimed invention. *See* Br. 9–16. As discussed below, we are not persuaded of reversible error by Appellants’ arguments.

Regarding Appellants’ first argument, we find that the proposed combination would at least be capable of functioning in the manner claimed,

i.e. providing tension to retain a bone dowel at a surgical site. Lambert discloses:

Disclosed herein is a method of anchoring a graft to a bone portion. The method comprises forming a first bore in a first bone portion, the first bore comprising a major opening, a minor opening, and a tapered sidewall disposed therebetween; disposing a first portion of the graft in the first bore; disposing a first portion of a bone cement precursor in the first bore, such that the first portion of the graft is substantially completely embedded in the first portion of bone cement precursor, and such that the first portion of bone cement precursor substantially conforms to the tapered sidewall of the first bore; and allowing the first portion of the bone cement precursor to set to form a first bone cement anchor disposed in the first bore, wherein the first portion of the graft is anchored in the first bone cement anchor and a second portion of the graft extends from the minor opening.

The method also comprises disposing the graft in the first bore with a selected amount of tension in the direction of the minor opening. The sidewall of the first bore comprises an angle of greater than or equal to about 20 degrees to about 45 degrees. In some embodiments, the bone cement comprises hydroxylapatite.

Lambert ¶¶ 11, 12; *see also id.* at Figs. 19–23; ¶ 72. Thus, Lambert not only discloses disposing a graft in two opposing bores and anchoring the graft with bone cement, but Lambert also discloses disposing the graft with an amount of tension in the direction of the minor opening of the bore. We find that placing the graft with some amount of tension would necessarily impart some retaining force on the bone cement filled bores. Thus, we agree with the Examiner's finding that Lambert, and the proposed combinations with Lambert, are inherently capable of producing a constant tension to retain a bone dowel at a surgical site, as claimed.

Regarding Appellants' remaining arguments, they are all premised on the fact that Lambert uses bone cement to anchor the graft in place while Appellants' invention is allegedly directed at a system that avoids permanent fixation means, such as screws, pins, nails, cement, etc. Br. 13–14. However, we agree with the Examiner's response to each of these arguments, i.e. each argument is unpersuasive at least because the claims as currently worded do not preclude the use of other fixation means such as the cement used by Lambert. *See* Ans. 3–8.

Appellants also attempt to overcome the rejection by expressly disavowing “**the use of setting bone cement as a requirement for anchoring the composite graft.**” Br. 11. We are not persuaded that the rejection should not be sustained based on this attempted disavowal of claim scope. In this matter, we are guided by our reviewing court which has stated “during patent prosecution *when claims can be amended*, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . [T]his way . . . uncertainties of claim scope [can] be removed, as much as possible, during the administrative process.” *In re Zletz*, 893 F.2d 319, 321–22 (Fed. Cir. 1989) (emphasis added). If Appellants wish to affirmatively limit the scope of their claims, the appropriate procedure for doing so while prosecution is open is through an amendment to the claims, and we decline to limit the claims based on Appellants' Brief. We also note that the Examiner has identified an inconsistency between Appellants' statement of disavowal and the description of the bone dowels in the Specification, which creates ambiguity regarding the extent of claim scope Appellants are attempting to disavow. *See* Ans. 7–8 (citing Spec. ¶¶ 52, 69, and 73).

Based on the foregoing, we are not persuaded of reversible error, and we sustain the rejections of claim 1 over Lambert in view of Boyce or Meredith. Appellants do not raise any separate arguments regarding any other rejections or any of the dependent claims, and thus, we sustain the rejections of dependent claims 2–17 and 34–38 for the same reasons.

CONCLUSION

For the reasons set forth above, we AFFIRM the rejections of claims 1–17 and 34–38.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED